Individual Safety Report

3171342-5-00-01

Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

McNEIL

MCNEIL CONSUMER PRODUCTS COMPANY
FORT WASHINGTON, PA 19034

Page ____ of ____

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	43 yrs or Date of birth: [redacted]	( )female (X)male	150 lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(X) death (mo/day/yr) 5/6/94
( ) life-threatening
(X) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr) 4/26/94

4. Date of this report (mo/day/yr) 11/30/94

5. Describe event or problem

Consumer report of husband taken to hospital on 4/26/94 with CHEST PAIN. Patient developed hepatic failure & KIDNEY FAILURE, was put on life support, & expired on 5/6/94. Consumer indicated that autopsy report listed cause of death as alcohol and TYLENOL poisoning. Additional information received 11/28/94: Medical records indicate on 4/22/94, patient experienced fever, abdominal & chest pain. On 4/26/94, patient had HYPOTENSION (hypotensive episode) in ER & was admitted with HEPATIC FAILURE & treated with with antibiotics & acetylcysteine discontinued 5/4/94. Patient developed kidney failure, ENCEPHALOPATHY with evidence of COAGULATION DISORDER (coagulopathy), & remained hypotensive, treated with pressors, TPN, blood products lactulose, & dialysis, & expired on 5/6/94. Final autopsy report lists principal diagnoses: massive centrilobular hepatic necrosis, diffuse alveolar damage of lungs, exudative phase & bronchopneumonia. Cause of death: massive hepatic necrosis probably due to acetaminophen toxicity.

6. Relevant tests/laboratory data, including dates

4/26/94 sys BP=70, ammonia=272, AST=5480, ALT=2251, PT=55.9, bili =8.9, WBC=31K per mm(3), serum acetaminophen level=5 mcg/ml; no source of sepsis identified, negative hepatitis serologies 5/5/94 ammonia=57, AST=143, ALT=166, PT=29, t.bili=29.1

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

alcoholic, alcoholic ulcer, history of hand surgery 2 months prior to hospitalization, no history of heart condition, treated once in 1990 for delirium tremens; allergic to penicillin

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 unknown TYLENOL product
#2 VICODIN®

2. Dose, frequency & route used

#1 1000mg(4/25), 500mg(4/26)
#2 1-2 prn qday

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 2days& unk amt 1-2 wks prior
#2 every day

4. Diagnosis for use (indication)

#1 toothache/fever
#2 unknown

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

6. Lot # (if known)

#1 Unknown
#2

7. Exp. date (if known)

#1 Unknown
#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

ethanol consumption of 12 pack/day for 23 years; 2-3 beers were consumed on 4/25/94

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

DEC 17 1998

2. Phone number

215-233-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
(X) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr) 11/28/94

5.
(A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
( ) Initial (X) follow-up # 1

8. Adverse event term(s)

DEATH
KIDNEY FAILURE
ENCEPHALOPATHY
HYPOTENSION
PAIN CHEST
LIVER FAILURE
COAGULATION DIS

9. Mfr. report number

0284020A

E. Initial reporter

1. Name, address & phone #

Dr. [redacted]
[redacted] Hospital
[redacted]

2. Health professional?

(X) Yes ( ) No

3. Occupation

physician

4. Initial reporter also sent report to FDA

( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.